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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,086	03/26/2001	Dale Baskin	7414.0043	2844

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
TUNG, JOYCE	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,086	BASKIN ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *51-67* is/are withdrawn from consideration.

5)☒ Claim(s) *26-50* is/are allowed.

6)☒ Claim(s) *1-18,20-26 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The applicant's response filed 8/26/2005 to the Office action has been entered. Claims 1-68 are pending. Claims 1-18, 20-50 and 68 are examined.

1. The rejection of claims 26-50 under 35 U.S.C. 112, second paragraph, in section 3(b)-(c) of the Office action mailed 5/27/2005 is withdrawn because of the argument.

2. Claims 1-18, 20-25 and 68 remain rejected under 35 U.S.C. 112, second paragraph in section 3(a) of the Office action mailed 5/27/2005.

a. Claims 1-18, 20-25 and 68 are vague and indefinite because the phrase "directly sequencing". It is unclear what is the definition of the phrase. Clarification is required.

The response argues that in the specification there is the disclosure that the amplification product could directly be used in sequencing reactions (See pg. 18, para 53 and 54). However, it is still unclear the phrase "directly sequencing" is defined in the specification.

3. Claims 1-18, 20-25 and 68 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pritham et al.. (J of Clinical Ligand Assay, 1998, Vol. (4), pg. 404-412) in view of Johnston-Dow et al. (6,103,465, issued August 15, 2000).

Pritham et al. disclose a rapid PCR method to monitor the amplification by detecting the fluorescent signal (See pg. 404, the abstract) involving using fluorescence probe (See pg. 405 column 2, second paragraph and pg 406 column 2 to pg. 409, column 1). The teachings of Pritham et al. are recited through out the limitations of claims 1-9, and 20-24, except that Pritham et al do not disclose the sequencing method used to detect a specific target nucleic acid as recited in the limitations of claim 1.

Pritham et al. also do not indicate the source of the DNA sample used as listed in claims 10-18, and 25 in the method.

Johnston-Dow et al. disclose a method for typing HLA class I gene and the method involving DNA sequencing techniques (See the Abstract and column 9, lines 9-22). The method is to provide for the specific DNA sequencing of HLA-A, HLA-B and HLA-C (See column 3, lines 19-22). Johnston-Dow et al. also disclose that any source of human nucleic acid can be used, for example, blood and lymphoblostoid cell lines (See column 6, lines 9-14) as recited in the limitations of claims 10, and 25. Johnston-Dow et al. further indicate that HLA typing is performed routinely in connection with many medical indications, the study of auto-immune disease and the determination of susceptibility to infectious disease (See column 1, lines 57-62). This teaching suggests the limitations of claims 11-18 in that the pathogen will be from a virus, prokaryote and eukaryote, the presence of the given target polynucleotide indicates the presence of the genetic disease or a specific allele which can indicate serotype.

It would have been prima facie obvious to an ordinary skill in the art at the time of the instant invention to combine the teachings of Pritham et al. and Johnston-Dow et al. to carry out the method as claimed with a reasonable expectation of success. The motivation is that the teachings of Pritham et al. indicate that fluorescent monitoring of PCR provides qualitative and quantitative information in that the qualitative information includes purity and identity (See pg. 404, column 1, last paragraph) and rapid cycle PCR is an ideal technique for fluorescence monitoring because temperature gradients within samples are minimized (See pg. 404, column 2, second paragraph) and the method of Johnson-Dow et al. is applied to the locus-specific nucleic acid amplification followed by sequence-specific detection of the amplified product for the DNA typing of HLA class I gene via DNA sequencing in that by sequencing the exons in

both directions, the effect of sequencing errors on the assignment of HLA type is minimized and the method greatly reduces the number of reagents and the complexity of the sequencing protocols required (See column 9, lines 29-37).

The response argues that the instant invention is to directly sequence at least one amplification product from the reaction composition comprising the fluorescent indicator or the intercalating fluorescent indicator and claims 1 and 68 would have not been obvious over Pritham in view of Johston-Dow et al.. However, Pritham et al do not disclose the sequencing method used to detect a specific target nucleic acid with the fluorescent indicator or the intercalating fluorescent indicator. Johston-Dow et al. disclose the method to distinguish between HLA-A,-B and –C genes with the use of locus-specific primer (See column 6, lines 57-67). The resulting amplicon is then subjected to a DNA sequencing method (See column 8, lines 63-67 and column 9, lines 1-8). The sequencing primer is labeled or dideoxy terminators has label attached in which the label is fluorescent label (See column 9, lines 9-22). The teachings of Johston-Dow et al. read on the limitations that at least one amplification product from the reaction composition is directly sequenced in the present of the fluorescent indicator. Thus, it would have been prima facie obvious to an ordinary skill in the art at the time of the instant invention to combine the teachings of Pritham et al. and Johnston-Dow et al. to carry out the instant invention. The rejection is maintained.

Allowable Subject Matter

4. Claims 26-50 are allowable.

5. The following is a statement of reasons for the indication of allowable subject matter:

Concerning claims 26-50, no prior art has been found teaching or suggesting a method of determining the presence and sequence of at least one target polynucleotide in a sample comprising using two reaction compositions which combine to nucleic acid from the sample in which a first reaction composition comprises amplification primers specific to at least one target polynucleotide and a second reaction composition comprises a fluorescent indicator and amplification primer specific to at least one target polynucleotide.

The closest prior art is the reference of Wittwer et al. (6,174670, issued Jan. 16, 2001). Wittwer et al. disclose methods of monitoring hybridization during polymerase chain reaction using two pairs of oligonucleotides and a nucleic acid binding fluorescent dye to monitor amplification of a selected template (See column 13, lines 62 to column 14, lines 29). However, Wittwer et al. do not disclose using two separate reaction compositions in a separate amplification reaction in which a first reaction composition comprises amplification primers specific to at least one target polynucleotide and a second reaction composition comprises a fluorescent indicator and amplification primer specific to at least one target polynucleotide.

Summary

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung JT
November 2, 2005

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
11/2/05